



ATTACHMENT A

Remarks

This application now includes claims 1, 10-26, 30, 31, and 39-67. All of the non-elected claims have been canceled and new claims 53-67 have been added in order to more clearly bring out the patentable features of the present invention.

Allowance of claims 17, 18, and 23 has been noted. However, for the following reasons, it is respectfully submitted that each of the independent claims 1, 19, 24, 30, 41, 46, 48, 53, 58, and 63 are patentable over the references of record, taken alone or in any combination.

All ten independent claims in this application relate, in one form or another, to an instrument or method for inserting an implant, generally of the type having upper and lower parts (wherein the lower part may be formed in one or two pieces) and/or to a spacer. The invention relates to instruments and methods for inserting this type of intervertebral implant. All of the claims recite various instrument recitations or method steps relating to this inventive concept.

The two primary references, Jackson and Winterbottom et al (hereinafter "Winterbottom"), are totally unrelated to this inventive concept. Accordingly, to the extent that either of these patents do not fully anticipate any claim, then they necessarily fail as an anticipating reference under § 102 and they would lack any teaching or motivation whatsoever for closing any gap between what is shown in one or both references and the respective claim.

Jackson has nothing to do with intervertebral implants. As best shown in Figure 9, the entire purpose and structure of Jackson is to manipulate a spinal rod such

as rod 7 which is connected to a bone screw 11. To the extent that the elements shown in Figures 1-9 include arms, pushers, and the like, they do not show in any way shape or form arms with ends constructed to cooperate in any way with any parts, much less upper and lower parts, of an intervertebral implant. Jackson is not capable of inserting anything into an intervertebral space; it does not even show an intervertebral space. It is not clear how the arms are closable towards each other but it is completely irrelevant because they do not move towards each other for any purpose, method, or with any structure related in any way to securing or inserting an intervertebral implant. The element 65 may be insertable into a recess of some kind. However, that recess has nothing to do with an intervertebral implant, but rather, only structure associate with the spinal rod 7. The spacer 20 has nothing to do with the spacer in the present invention which is inserted between upper and lower parts (not merely upper and lower arms) to limit movement of the upper and lower parts towards each other. Jackson does not even have upper and lower parts.

The Examiner notes that statements of intended use are essentially not given patentable weight. However, for the reasons set forth below, each and every independent claim includes numerous structural features which are not present in Jackson. Similarly, the statement that the method steps would have been inherently carried out by the operation of the device is completely erroneous because the device is a completely different device which performs steps related to spinal rods and the like, none of which are method steps relating to inserting an implant of the type described. Thus, not only are the method steps of the claims not remotely inherent in the operation

of the Jackson device, but instead they are not in any way even remotely suggested by the operation of the device shown in the Jackson patent.

Winterbottom is also totally unrelated to the present invention. Winterbottom deals with a device for inserting a one piece fusion implant. There is no structure whatsoever for interacting in any way with upper and lower parts of an implant and there are no arms and free ends which engage such an implant, either as a device or as a method. The Examiner refers to a pair of arms as shown in Figure 68. The engagement of these arms with an implant is shown in Figure 17 wherein the elements 174 and 174' engage a one piece fusion implant. To the extent that the Examiner is discounting statements relating to the type of implant, the Examiner is erroneously dismissing statements of structure and the relationship between elements (which is structure) by not giving same patentable weight. Clearly, with respect to the method claims, Winterbottom's device for inserting a one piece fusion insert could not be more remote, unrelated, and fail to anticipate the specific method steps which are directed to inserting an implant of the type described with upper and lower parts, with various engagements of the instrument with the upper and lower parts.

With respect to claim 1, Jackson does not show an instrument for inserting an intervertebral implant. Rather, it is entirely concerned with mounting a spinal rod, element 7 in Figure 9, which is never located in an intervertebral space. There are no upper and lower arms closable towards each other and no arms which enter a recess or secure an implant between them. There are no arms which are separable away from each other for removal of an implant. There are no arms having at their outer ends a recess engaging structure for the recess of an intervertebral implant. Winterbottom

shows an instrument with jaws 440 and 442 which receive a one piece fusion implant. These are not upper and lower arms, they are not constructed to close so as to enter recesses in the top and bottom of the implant to secure the implant, nor are they separable away from each other for removal of the implant. At best, the jaws 440 and 442 grab the sides of a one piece fusion implant. The arms do not include at their outer ends recess engaging portions for engaging recesses in the top and bottom of the implant.

Claim 19, as further amended to more clearly bring out the features of the present invention, comprises a pair of arms including an upper arm and a lower arm having forward ends constructed to secure upper and lower parts of an intervertebral implant. Jackson is completely devoid of any of these teachings as it does not show upper and lower arms and does not relate in any way to an implant having upper and lower parts. In Winterbottom, even if one assumes that the jaws 440 and 442 are upper and lower arms, they are not constructed to secure upper and lower parts of an intervertebral implant since they do not show an implant of the type having upper and lower parts. Additionally, Winterbottom shows no spacer between the arms constructed to move between upper and lower parts, as of course is impossible since Winterbottom does not show an implant having upper and lower parts.

Claim 24 recites an instrument having a pair of pivotally connected arms. This immediately eliminates Jackson which does not show pivotally movable arms. Winterbottom does not show pivotally connected arms which are constructed to close towards each other to secure upper and lower parts of an intervertebral implant between them since there is no teaching in Winterbottom of such an implant. Nor does

Winterbottom show upper and lower arms constructed to engage the upper and lower parts, since no such upper and lower parts are shown in Winterbottom.

Concerning claim 30, the Examiner has dismissed the method claims out of hand as reciting nothing more than the inherent function of Jackson and Winterbottom. As discussed at length above (and below), neither Jackson nor Winterbottom disclose the type of instrument with which the present invention is concerned, and thus it is completely erroneous to even suggest that operation of these instruments inherently discloses the claimed method. Moreover, to the extent that various limitations of the apparatus claims might have been considered as function, functional-type statements are the essence of a method claim such that they should definitely be given maximum weight. Claim 30 recites a method of inserting an intervertebral implant of the type having an upwardly facing upper recess and a downwardly facing lower recess. Jackson does not show any type of implant and Winterbottom does not show this type of implant and hence Winterbottom cannot remotely begin to show or suggest the method steps of claim 30. Claim 30 further recites moving the forward ends of the instrument into upwardly and downwardly opening recesses. Winterbottom shows jaws which engage the side of a one piece fusion implant; they clearly do not move into upwardly and downwardly opening recesses.

Claim 41 also recites a method which is completely different from and in no way suggested by Jackson or Winterbottom. As noted above, Jackson is such a completely different instrument and relates to an item (a spinal rod) so different from an intervertebral implant that Jackson should not even be considered as a basis for a rejection. Claim 41 recites a method relating to an implant having upper and lower

parts. This completely differentiates it from Winterbottom which relates to a totally different implant, namely a one piece fusion implant. Since Winterbottom does not have upper and lower parts, it cannot possibly have or inherently suggest the step of securing upper and lower parts to upper and lower arms, which it also does not have. Moreover, Winterbottom does not have any kind of spacer. The screw 438 in Figure 68 is not a spacer; and of course the screw cannot enter a space between upper and lower parts which it does not even have.

Claim 46 is another method claim which is not remotely suggested or inherent in the instruments of Jackson and Winterbottom. Once again, Jackson must be dismissed out of hand as not relating in any way to the subject matter of this claim, inserting an implant of the type having upper and lower parts. Moreover, Winterbottom, while at least relating to an implant, is still totally irrelevant to the method steps of claim 46 in that it shows a one piece implant, not an implant having upper and lower parts; and Winterbottom does not show any spacer (the screw 438 is not a spacer) and there are clearly no upper and lower arms with a spacer between (the non-existent) upper and lower parts:

Method claim 48 also relates to an intervertebral implant having upper and lower parts which is so totally dissimilar to Jackson, which does not even show any kind of implant, that any rejection based on Jackson must necessarily be withdrawn. Although Winterbottom shows an implant, it is a one piece implant, not an implant of the type called for in the claim. Nor does Winterbottom show upper and lower arms. Instead, it shows two jaws on the left and right side of the one piece implant. Since Winterbottom shows only a one piece implant, there is no suggestion or motivation whatsoever for

rotating the arms 90°, and even then the reference would not be relevant because there are in fact no upper and lower parts.

New independent claims 53, 58, and 63 have been added in order to more clearly describe patentable aspects of the present invention in light of the complete lack of relevance of the cited references, Jackson and Winterbottom to the basic concepts and features of the present invention.

Claim 53 calls for an instrument for inserting an insert of the type having upper and lower parts. It calls for upper and lower arms having free ends with a structure for engaging the upper and lower parts. Jackson clearly does not show such arms or such parts. Winterbottom also does not show arms having free ends for engaging upper and lower parts. Additionally, Winterbottom clearly does not show a spacer located between the upper and lower arms. As noted, the screw 438 is not a spacer, and in any event it certainly cannot move into a non-existent space between its non-existent upper and lower parts.

Claim 58 recites in combination form the instrument, its arms, and the implant having the upper and lower parts. Additionally, claim 58 recites a spacer located between these arms and movable into a space between the upper and lower parts. Jackson must be dismissed out of hand as being totally irrelevant to the subject matter of this claim. Similarly, Winterbottom, although related to the general subject matter of implants, does not show an instrument with upper and lower arms or an implant having upper and lower parts. Nor does Winterbottom show any arms with free ends with a structure for engaging upper and lower parts. Nor does Winterbottom show any kind of spacer.

Method claim 63 relates to a method for inserting an implant of the type having upper and lower parts. This immediately excludes Jackson which is totally irrelevant and it also excludes Winterbottom which is totally irrelevant to the concept of dealing with an implant of the type having upper and lower parts. Nor does Winterbottom suggest steps of placing anything, much less a spacer, between its non-existent upper and lower parts and moving the spacer between these parts.

For all of the above reasons, all of the independent claims in this application cannot properly be rejected as anticipated by Jackson or Winterbottom.

Similarly, concerning the rejections under § 103, Jackson and Winterbottom are so different from each other and so totally remote from the present invention that there is no teaching or motivation whatsoever to combine these two very different references to arrive at the present invention. To do so would be pure hindsight, and even then it is not even seen how any combination of these two different references is even possible, much less proper.

In view of the above it is respectfully submitted that this application is now in condition for allowance, which action is promptly and respectfully solicited.

END REMARKS